DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-810/S-067 and S-080

Astra-Zeneca LP
Attention: Barbara Blandin
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Blandin:

Please refer to your supplemental new drug application (S-067) dated November 15, 1999, received November 16, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec® (omeprazole) Delayed-Release Capsules.

Your submission of April 9, 2003 constituted a complete response to our December 30, 2002 action letter.

Also, please refer to your supplemental new drug application (S-080) dated April 9, 2003, received April 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec® (omeprazole) Delayed-Release Capsules.

These supplemental new drug applications provide for the addition of "blurred vision" and "eye irritation" to the **ADVERSE EVENTS** section (S-067), and changes to the **PRECAUTIONS, Drug Interactions** section, specifically, drug interactions related to warfarin (S-080), of the package insert.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, submitted April 11, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-810/S-067 and S-080." Approval of these submissions by FDA is not required before the labeling is used.

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html. To expedite review of this patent

declaration form, we request you submit an additional copy of the form to these applications and to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Melissa Hancock Furness, Regulatory Project Manager, at (301)-827-7450.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick
10/9/03 05:16:58 PM
for Dr. Robert Justice